Congress of the United States

Washington, DC 20515

December 15, 2022

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

We are writing to encourage the Centers for Medicare & Medicaid Services (CMS) to issue the Transitional Coverage for Emerging Technologies (TCET) proposed rule by the end of 2022. Following repeal of the Medicare Coverage for Innovative Technology (MCIT) rule last year, CMS has expressed repeated commitment for establishing a pathway to facilitate Medicare beneficiary access to innovative and emerging medical technologies. While we remain concerned that the repeal of MCIT may hinder patient access to U.S. Food and Drug Administration (FDA) approved breakthrough treatments, we commend the agency for its continued commitment to this important policy goal and appreciate inclusion of this rule in the 2023 Unified Regulatory Agenda.

Medicare beneficiaries suffering from life-threatening diseases, disabilities, injuries, and chronic illnesses should have timely and equitable access to innovative technologies. Unfortunately, far too many Medicare patients today face challenges accessing the technologies and treatments they need due to unnecessary delays in establishing consistent Medicare coverage policies for new medical devices and diagnostics.

We firmly believe a successful implementation of a TCET rule that includes an independent transitional coverage pathway for breakthrough devices that have been proven safe and effective by the FDA. Such a process will meaningfully improve the Medicare coverage process for emerging technologies and will ensure that Medicare beneficiaries, especially those in rural and medically underserved communities, can access the innovative treatments they need once they become available. To that end, we respectfully urge you to move quickly to help improve the lives of the many Medicare beneficiaries who stand to gain from timely access to emerging and innovative technologies by issuing the TCET proposed rule by the end of 2022.

We thank you for your consideration of this request, and appreciate your continued commitment to Medicare beneficiary access to innovative medical devices and diagnostics. If you have any questions, please contact Aisling McDonough at aisling.mcdonough@mail.house.gov.

Sincerely,

Anna G. Eshoo

Member of Congress

Brett Guthrie

Member of Congress

Suzan K. DelBene Member of Congress Brad R. Wenstrup, D.P.M.

Member of Congress